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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. <i>mk</i>
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NAME OF INVENTOR (Last, first, middle initial)

NAME OF ATTORNEY (Last, first, middle initial)

NAME OF INVENTOR  
CATTELL MEMORIAL INSTITUTE  
FEDERAL BUREAU OF INVESTIGATION  
P.O. BOX 1000  
BETHESDA, MD 20812

INVENTOR'S ADDRESS

EXAMINER

MAILING DATE

ART UNIT

PAPER NUMBER

10

1731

DATE MAILED:

02/12/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/209,541**

Applicant  
**Gutowska**

Examiner  
**Jeffrey Mullis**

Group Art Unit  
**1711**



☒ Responsive to communication(s) filed on Feb 8, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-46 is/are pending in the application.
- Of the above, claim(s) 13-30 and 37-46 is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-12 and 31-36 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claims \_\_\_\_\_ are subject to restriction or election requirements.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3, 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's drawing sheet 2 containing Figure 3 is missing from the file. Applicant should therefore resubmit Figure 3.

Applicant's election without traverse of Group I, claims 1-12 and 31-36 in Paper No. 7 is acknowledged.

Applicant's election of species polysaccharide in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-12 and 31-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear if the "hydrophilic comonomer" is optional in that claim 1 recites that this material is present in an amount of "less than about 10 mole percent". Since the term "less than about" embraces 0, this claim can be interpreted such that comonomer ii is optional. With regard to claim 31, this claim is ambiguous as to whether the term "copolymerized with hydrophilic comonomers" is intended to refer to the homooligomers of methacrylamide derivatives or refers to the entire Markush group of side chains "b".

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sassi et al. (USP 5,631,337).

Sassi et al. disclose "thermal reversible hydrogels" having a narrow melting range transition (note the paragraph bridging columns 5 and 6) and containing acrylamide monomers (column 7

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lines 30-40). The material may be used in controlled release compositions at column 7 lines 18-20. With regard to the characteristic of "substantially no syneresis", this is assumed to be inherent.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bae et al. (USP 5,262,055).

Bae et al. disclose a gelling matrix containing a bioactive agent which is surrounded by a membrane (Abstract). Applicant's monomers are disclosed at the paragraph bridging columns 8 and 9. The membrane has a molecular weight cutoff of 100,000 which is well above any "minimum gelling molecular weight cutoff" at the paragraph bridging pages 6 and 7 and any polymers having a molecular weight below this limit if it existed would be eliminated by diffusing out of the membrane during use.

It is possible that applicant intends that his claims exclude low molecular weight polymer, however for the reasons set

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out above it is the position of the Examiner that low molecular weight polymers are inherently excluded by Bae et al.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

Claims 1-12 and 31-36 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hoffman et al. (USP 5,998,588).

Hoffman et al. disclose a material produced by generating a polymer of derivatized acrylamide with reactive end groups which are subsequently reacted with streptavidin to form a graft. Note column 32 lines 10-34. Note in particular that all of the material is purified by GPC at column 32 lines 31-34 and therefore contain no low molecular weight material. With regard to applicant's characteristics, these are assumed to be inherent.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re

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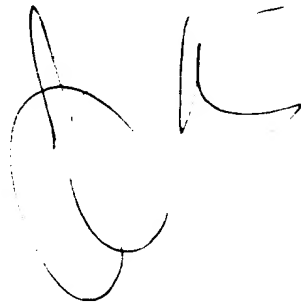
Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

Any inquiry concerning this communication should be directed to Jeffrey Mullis at telephone number (703) 308-2820.

J. Mullis:cdc

January 29, 2001

**Jeffrey Mullis**  
**Primary Examiner**  
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A handwritten signature in black ink, appearing to be 'J. Mullis', written in a cursive style.